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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/002,417 | 10/25/2001 | Henri Hansson | 23544-7003 | 2623 |

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EXAMINER

WEDDINGTON, KEVIN E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1614

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/002,417

Applicant(s)
Hansson et al.

Examiner
Kevin E. Weddington

Art Unit
1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 26, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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Claims 1-48 are presented for examination.

Applicants' information disclosure statement filed February 11, 2002 has been received and entered.

Applicants' election filed July 26, 2002 in response to the restriction requirement of June 28, 2002 has been received and entered. The applicants elected the invention described in claims 1-48 (Group I) without traverse.

Claims 49-64 were canceled.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 U.S.C. § 112

Claims 1, 4-13, 16-22, 25-31, 34-40 and 43-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' specification does not contain any test results or experimental data showing a predetermined amount of starch will, in fact, prevent dysglucaemia in a human not presently at risk of or predisposed to developing such a disorder.

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Claims 2, 12-21, 23, 32 and 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The remaining claims 14, 23, 32 and 41 are also rendered indefinite to the extent that they incorporate the above terminology.

Regarding claims 12-21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 40-48, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 23, 32 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24906, hereby known as Kaufman (B1).

Kaufman teaches the use of complex carbohydrates to diminish hypoglycemia in patients with diabetes mellitus. The reference teaches the complex carbohydrate is cornstarch (uncooked), the applicant uses starch too. The reference teaches the cornstarch is taken by the diabetic patient over a period of six to eight hours (see page 5, lines 14-18) the same as applicants' regimen in claim 41. The reference also teaches the cornstarch are formulated into sustained release tablets, pills, lozenges and the like. (See page 7, lines 5-8).

The instant invention differs from the cited reference in that the cited reference does not teach the starch is encapsulated in a substance disclosed in claim 23.

However, the cited reference , as taught above supra that the cornstarch is formulated

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into tablets, pill, lozenges, and the like. In the art of formulation of tablets, the substance disclosed in claim 23 are well-known binders for such processes.

The instant invention differs from the cited reference in that the cited reference does not teach the patient suffering from hypoglycemia are athletes as disclosed in claim 14. However, to administer the instant invention to diabetic athletes would have been clearly obvious since diabetes can affect any human, thus administering the invention to athletes (diabetic) is well-known in the art.

Claim Rejections - 35 U.S.C. § 103

Claims 3, 15, 24, 33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelsen 'et al. (C).

Axelsen et al. teach a method for improving tolerance in humans suffering from impaired glucose tolerance including both IGT and diabetes mellitus type-2 with a therapeutic amount of slow-release starch at bedtime. (See the abstract) Clearly the reference suggests the starch is use to control blood glucose, the same as glycemic control in a diabetic patient.


The instant invention differs from the cited reference in that the cited reference does not teach the diabetic patients are athletes as disclosed in claim 15. However, the Examiner does not see why administering the instant invention to diabetic athletes is novel since anybody can be diabetic including athletes.

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Claims 1-48 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington

November 14, 2002